



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/698,070

Applicant: Kaye et al.

Filed: October 20, 2003

TC/AU: 1623

Examiner: Tracy Ann Vivlemore

Docket No.: 221749 (DHHS Reference No. E-086-2003/0-US-01)

Customer No.: 45733

**DECLARATION UNDER 37 C.F.R. § 1.132 OF FREDERIC J. KAYE, M.D.
AND TAKEFUMI KOMIYA**

We, Frederic J. Kaye, M.D. and Takefumi Komiya, do hereby declare:

1. We are joint inventors of the subject matter disclosed and claimed in the above-captioned patent application (referred to herein as "the present invention"). We are the only inventors of the above-captioned patent application.

2. We understand that the U.S. Patent and Trademark Office has rejected the pending claims of the above-captioned patent application as unpatentable over Tonon et al., *Nature Genetics*, 33: 208-213 (2003). We are co-authors on this publication.

3. Technical articles typically list as co-authors those individuals who rendered some assistance or performed some work in connection with a project, irrespective of whether they were merely acting at the direction and under the supervision of someone else and/or whether they were merely providing technical support. Moreover, individuals may be listed as co-authors on a technical article if they were involved in some aspect of the project described in a technical article irrespective of whether their involvement formed a part of the later claimed invention. As regards the aforementioned publication, Giovanni Tonon, Sanjay Modi, Lizi Wu, Akihito Kubu, Amy B. Coxon, Kevin O'Neil, Kristen Stover, Adel El-Naggar, James D. Griffin, and Ilan R. Kirsch were involved in aspects of the research unrelated to the claimed invention or, to the extent such individuals were involved in related research, acted at our direction, and, in some instances, under our supervision, and provided technical support in carrying out the experimental plans set forth in the aforementioned publication. As

TV
4/4/06

Application No. 10/698,070

Declaration of Frederic J. Kaye, M.D.

such, these individual did not make any intellectual contribution to the conception of the claimed invention.

4. We hereby declare that all statements made herein of our own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

Frederic J. Kaye, M.D.

Date: 1/21/2006

Takefumi Komiya
Takefumi Komiya